PRODUCT MANUAL FOR

MEDICAL ELECTRICAL EQUIPMENT PART 2 PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE SECTION 12 CRITICAL CARE VENTILATOR ACCORDING TO IS 13450 (PART 2/SECTION 12): 2023

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो) अनुरूपता मूल्यांकन (विनियम, 2018 की योजना -I के तहत प्रमाणन के संचालन में एकरूपता और पारदर्शिता के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता हैI

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations,2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification.

1.	**मानक संख्या** **IS No.**	:	IS 13450 (Part 2/ Sec 12): 2023
	शीर्षक **Title**	:	Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 12 Critical Care Ventilator
	संशोधनों की संख्या **No. of amendments**	:	Nil
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	Components – As per Cl 4.8 of IS 13450 (Part 1 / Sec 12)
b)	**समूहीकरण दिशानिर्देश Grouping Guidelines**	:	Please refer **ANNEX – A**
c)	**नमूने का परिमाण** **Sample Quantity**	:	1 machine (with all the accessories)
3.	**परीक्षण उपकरणों की सूची** **List of Test Equipment**	:	Please refer **ANNEX – B**
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	Please refer **ANNEX – C**
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**	:	Please refer **ANNEX – D**

6.	**लाइसेंस का दायरा /Scope of the Licence:**

"License is granted to use Standard Mark as per ***IS 13450 (Part 2/Sec 12):2023*** with the following scope:

Name of the product	Medical electrical equipment: Part 2 particular requirements for the basic safety and essential performance: Section 12 Critical Care Ventilator
Model(s)	
Type	Stationary (or) Fixed / Mobile / Portable / Hand-held
Rating	Rated Voltage …..V (or) Rated Voltage Ranges(s) ……V, ac Frequency 50 Hz, Single phase / Three Phase, Rated Current …. A (or) Input power ……. W / VA
Protection against electric shock	Class – I / Class – II
Mode of Operation	Continuous / Non-Continuous
Protection against harmful ingress of water or particulate matter	
Suitability for use in oxygen rich environment	Suitable/ Not suitable
Method of Sterilization	(To be declared by the manufacturer)
Declarations (To be declared by the manufacturer)	
Type of Gas input(s)	With / without Pressurized Gas input
Connection type	to be connected with to a medical gas pipeline system / not to be connected to a medical gas pipeline system
Inflation type	Volume-controlled inflation-type / Pressure-control inflation-type / Other inflation type (Declare the parameter here)
Maximum Limited Pressure ($P_{LIM\ max}$)	
Maximum working pressure ($P_{W\ max}$)	
Rated range of gas pressure	
Display loops	Pressure-volume loops / Flow-volume loops / Any other (to be declared)
Timed ventilatory pause	Expiratory pause / Inspiratory pause / Any other (to be declared)
Any other declerations (to be declared by the manufacturer)	
Accessories (provided with the Medical Equipment that are directly in contact with the patient)	
Accessories (provided with the Medical Equipment that are not directly in contact with the patient)	

ANNEX -A

Grouping Guidelines

1. Manufacturer shall submit declaration for each of the model of 'Critical Care Ventilators' they intend to cover in the scope of licence. Further, the manufacturer shall also declare the essential accessories (if any) supplied along with the model.

2. For Grant of Licnce/ Change in Scope of Licence, each 'Model' of 'Critical Care Ventilators' is to be tested.

3. During the operation of the Licence, BO shall ensure that all the model(s) covered in the Scope of the Licence are tested in rotation to the extent possible.

ANNEX- B
List of Test Equipment & Documents
Major test equipment required to test as per the Indian Standard

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Power Input, 4.11	Power Input Test Apparatus/Power Analyzer / Multimeter
2.	Ambient Temperature 5.3	Temperature & Air Velocity Meter
3.	Accessible Parts 5.9.2	Test Finger with accessibility test apparatus
4.	Humidity preconditioning treatment, 5.7	Conditioning chamber with temperature and humidity chamber
5.	Durability of markings, 7.1.3	Distilled water, ethanol 96%, Isopropyl alcohol, Stop watch
6.	Earth Leakage Current, 8.7.4.5, Touch Current, 8.7.4.6, Patient Leakage Current, 8.7.4.7	Figure 13 to Figure 18, Leakage Current Tester, metal foil
7.	Impedance and current carrying capability, 8.6.4	AC/DC voltage source, Multimeter/Earth Resistance Tester
8.	Dielectric Strength, 8.8.3	High Voltage Tester
9.	Creepage Distances And Air Clearances 8.9	Vernier Caliper, Filler Gauge
10.	Volume control breath type, 201.12.1.101	Gas flow analyser, Test lung, stopwatch, Accompanying documents
11.	Pressure control breath type, 201.12.1.102	
12.	Accuracy of delivered volume, 201.12.1.103	
13.	Response of the VENTILATOR to an increase in O2 concentration, 201.12.1.104	
14.	Measurement of AIRWAY PRESSURE, 201.12.4.102	
15.	Measurement of expired volume and low-volume ALARM CONDITIONS, 201.12.4.103.1, 201.12.4.103.2	
16.	Maximum limited pressure protection device, 201.12.4.104	
17.	High pressure alarm condition and protection device, 201.12.4.105	
18.	PEEP alarm conditions, 201.12.4.106	
19.	Obstruction alarm condition, 201.12.4.107	
20.	Volume control breath type, 201.12.1.101	
21.	Pressure control breath type, 201.12.1.102	

Note 1: The above list is indicative only and may not be treated as exhaustive.

Note 2: The licensee shall maintain a Technical file and Risk Management File as per the provisions of IS 13450 (Part 2/ Sec 12): 2023 for each model in the scope of license.

Note 3: The Technical File and Risk Management File shall be maintained by the licensee till the End of Life for each model.

ANNEX C

SCHEME OF INSPECTION AND TESTING

1. QUALITY ASSURANCE PLAN

1.1 It is expected that manufacturers (licensees/applicants) will implement a Quality Assurance Plan i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.

1.2 The manufacturers shall define a Quality Assurance Plan defining the control unit (i.e. lot/batch etc.) and the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and submit the same to BIS Branch Office for information. The manufacturer shall comply with the same and maintain test records in accordance with para 2.4.

1.3 RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT:

1.3.1 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in Table 1.

1.3.2 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan. Alternatively, the manufacturer has the option of adherence to the quality plan as per levels of control recommended in column 3 of Table 1.

1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

2. ENSURING COMPLIANCE THROUGH TESTING-

It is expected that manufacturers (licensees/applicants) will establish a suitably equipped and staffed in house laboratory (In house testing facility) for testing at least those parameters of the Indian Standard which require routine testing for ensuring quality of the product. This includes in-process controls as may be defined and put in place by the manufacturer and testing parameters/requirements which can only be performed in the factory.

2.1 For the guidance of manufacturers, Table 1 giving the recommended levels of control is given below. Column 2 of Table 1 indicates routine tests where test equipment is required in house as "R" or other tests which can be subcontracted as "S". Subcontracting is permitted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.2 For MSME manufacturers, the requirement of maintaining a laboratory/in-house testing facility for routine tests (indicated as "R" in Column 2 of Table 1) is also optional.

2.2.1 MSME manufacturers may utilize common cluster based facilities as per guidelines for the utilization of cluster based test facilities by MSMEs or the provisions of Sharing of testing facilities or get testing done from BIS recognized/empaneled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.3 Large Scale manufacturers shall maintain an in-house laboratory equipped at least with test facilities for routine tests (indicated as "R" in Column 2 of Table 1), where different tests given in the specification shall be carried out in accordance with the method given in the specification. They shall also implement a calibration plan for the in-house test equipment.

2.3.1 Alternatively, in lieu of an in-house laboratory, large scale manufacturers can also utilize the provisions of Sharing of testing facilities as per the Guidelines for Grant of Licence available on BIS website www.bis.gov.in. (Under Conformity Assessment>Product Certification Process). Even for subcontracted tests, provisions for sharing of testing facilities can be utilized.

2.4 TEST RECORDS- The manufacturers maintaining an in-house laboratory or utilizing common cluster based facilities or shared test facilities shall maintain test records for the tests carried out to establish conformity. For the tests being subcontracted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

2.4.1 TECHNICAL FILE- Licencee shall maintain a Technical File for each model being manufactured by them. The Technical file shall be submitted to BIS at the time of Grant of Licence/ inclusion/ surveillance.

2.4.1.1 The Technical File shall be maintained till the End of Life of the model.

2.4.1.2 Licencee shall declare the frequency for periodic review in Technical file to BIS and record of review to be maintained. In case of any change in the Technical file due to any periodic review/ change in the product, the licencee shall inform the same to BIS at the earliest and provide the copy of the latest version of Technical File to BIS within 30 days of issue of the revised/ modified Technical File.

2.4.1.3 For changes in the product which shall affect the Scope of the Licence, the modified product shall be treated as a different model and separate Technical File shall be maintained for the same.

2.4.1.4 The technical file shall consist of the following documents:

- A general description of the product;
- Product Manual and/ or Instructions for use;
- Instructions for repair/ service for the product/ components, if required;
- Frequency of periodic repair/ service for the product/ components, if required;
- Conceptual product design and manufacturing drawings and, where appropriate, list of components, electrical circuit design, etc with descriptions and explanations needed for the understanding of these drawings;
- A list of the all Indian/ International standards applied in full or in part during the conformity assessment process with copy of test certificate/ test report;
- Test reports/ Test Certificates and risk assessment file for the product and/ or components as per relevant Clauses of the Indian Standard;
- Copies of conformity assessment documentation for critical product components;
- Copy of BIS licences for the product/ components, wherever applicable;
- A copy of the Declaration of Conformity for other International Standards;
- Other documents, if found necessary by the manufacturer and/ or by BIS may also be a part of the Technical File

2.4.2 RISK MANAGEMENT FILE- The licencee shall maintain a Risk Management File for each model in the scope of licence as per the requirement of IS 13450 (Part 2/ Sec 12): 2019/IEC 60601-2-12: 2018. The Risk Management File shall be submitted to BIS at the time of Grant of Licence/Inclusion/Surveillance.

2.4.2.1 The Risk Management File shall be maintained till the End of Life of the model.

2.4.2.2 Licencee shall declare the frequency for periodic review of Risk Management File and record of review in the file to be maintained. In case of any change in the Risk Management File due to any periodic review/ change in the product, the licencee shall inform the same to BIS at the earliest and provide the copy of the latest version of Risk Management File to BIS within 30 days of issue of the revised/ modified Technical File.

3. PACKING AND MARKING - The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each Critical Care Ventilators provided always that the material so marked conforms to each requirement of the specification.

3.1 Packing and Marking shall be done as per Cl. 201.7 of IS 13540 (Part 2 / Sec 12): 2023.

3.2 Additional Marking requirements: The following additional marking requirement shall be marked on each Critical Care Ventilators and its packaging:

a) "For BIS certification details please visit www.bis.gov.in"

4. HYGIENIC CONDITIONS (if applicable) – NA.

5. REJECTION - All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark. Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act,2016.

TABLE-1

(1)				(2)	(3)		
Test Details				**Test Equipment requirement R: Required (or) S: Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Method**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**				
201.4	**General requirements**						
201.4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS	4.1	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.4.2	Risk management process for ME equipment or ME systems	4.2	IS 13450 (Part 1)	R	One	Each Medical Equipment	
201.4.3	**Essential Performance**						
201.4.3.101	Additional requirements for essential performance	201.4.3.101 Table 201.101	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.4.4	EXPECTED SERVICE LIFE	201.4.4	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.4.5	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	201.4.5	IS 13450 (Part 2/ Sec 12)	R			

201.4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	201.4.6	IS 13450 (Part 2/ Sec 12)	R			
201.4.7	SINGLE FAULT CONDITION for ME EQUIPMENT	13.1 13.2	IS 13450 (Part 2/ Sec 12)	S			
201.4.8	Components of ME EQUIPMENT	201.4.8	IS 13450 (Part 2/ Sec 12)	S	One	Each Consignment	No further testing if accompanied with Test Certificate or ISI Mark or covered in Risk Management file
201.4.9	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	201.4.9	IS 13450 (Part 2/ Sec 12)				
4.10	**Power supply**						
4.10.1	Source of power for ME EQUIPMENT	4.10.1	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	4.10.2	IS 13450 (Part 1)	R			
4.11	Power input	4.11	IS 13450 (Part 1)	R			
201.4.11.101	Additional requirements for pressurized gas input	201.4.11.101	IS 13450 (Part 2/ Sec 12)	R			
201.5	**General requirements for testing ME EQUIPMENT**						
201.5.101.1	Ventilator test conditions	201.5.101.1	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.5.101.2	Gas flowrate and leakage specifications	201.5.101.2	IS 13450 (Part 2/ Sec 12)	R			
201.5.101.3	Ventilator testing errors	201.5.101.3	IS 13450 (Part 2/ Sec 12)	R			

201.7	**ME Equipment identification, marking and documents**						
201.7	ME Equipment Identification, marking and documents	7	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	7.2 201.7.2	IS 13450 (Part 1) IS 13450 (Part 2/Sec 12	R			
201.7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts	7.3	IS 13450 (Part 1)	R			
201.7.4	Marking of controls and instruments	7.4 201.7.4.3	IS 13450 (Part 1) IS 13450 (Part 2/Sec 12)	R			
201.7.5	Safety signs	7.5		R			
201.7.6	Symbols	7.6		R			
201.7.7	Colours of the insulation of conductors	7.7	IS 13450 (Part 1)	R			
201.7.8	Indicator lights and controls	7.8 201.7.8.2	IS 13450 (Part 1) IS 13450 (Part 2/Sec 12)	R			
201.7.9	ACCOMPANYING DOCUMENTS	7.9 201.7.9	IS 13450 (Part 1) IS 13450 (Part 2/Sec 12)	R			
201.8	**Protection against electrical hazards from ME Equipment**						
8.1	Fundamental rule of protection against electric shock	8.1	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.2	Requirements related to power sources	8.2	IS 13450 (Part 1)	R			
8.3	Classification of APPLIED PARTS	8.3	IS 13450 (Part 1)	R			
8.4	**Limitations of voltage, current or energy**						

8.4.2 (a)	The currents from, to or between Patient connections	8.7.4	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.4.2 (b)	The Leakage Currents from, to or between Accessible parts	8.7.4	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.4.2 (c)	Other accessible parts	8.4.2	IS 13450 (Part 1)	S	One	Once in 03 year	Refer Note 1
8.4.2 (d)	Internal parts that are accessible	8.4.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.4.3	ME equipment intended to be connected to a power source by a plug	8.4.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.4.4	Internal capacitive circuits	8.4.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.5	**Separation of Parts**						
8.5.1.2	Means of Patient Protection (MOPP)	8.5.1.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	8.5.1.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.5.2	Separation of PATIENT CONNECTIONS	8.5.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.5.3	MAXIMUM MAINS VOLTAGE	8.5.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.5.4	WORKING VOLTAGE	8.5.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.5.5	DEFIBRILLATION - PROOF APPLIED PARTS	8.5.5	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1

8.5.5.1	Defibrillation Protection	8.5.5.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.5.5.2	Energy Reduction Test	8.5.5.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.6	**Protective earthing, functional earthing and potential equalization of ME EQUIPMENT**						
8.6.1	Applicability of requirements	8.6.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.6.2	PROTECTIVE EARTH TERMINAL	8.6.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.6.3	Protective earthing of moving parts	8.6.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.6.4	Impedance and current-carrying capability	8.6.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.6.5	Surface Coatings	8.6.5	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.6.6	Plugs and sockets	8.6.6	IS 13450 (Part 1)	R			
8.6.7	POTENTIAL EQUALIZATION CONDUCTOR	8.6.7	IS 13450 (Part 1)	R			
8.6.8	FUNCTIONAL EARTH TERMINAL	8.6.8	IS 13450 (Part 1)	R			
8.6.9	CLASS II ME EQUIPMENT	8.6.9	IS 13450 (Part 1)	R			
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**						
8.7.1	General Requirements	8.7.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1

8.7.2	SINGLE FAULT CONDITIONS	8.7.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.7.3	Allowable values	8.7.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.7.4	Measurements	8.7.4 201.8.7.4.7	IS 13450 (Part 1) IS 13450 (Part 2/Sec 12)	S	One	Once in 03 years	Refer Note 1
8.8	Insulation						
8.8.2	Distance through solid insulation or use of thin sheet material	8.8.2	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.8.3	Dielectric strength	8.8.2	IS 13450 (Part 1)	R			
8.8.4	**Insulation other than wire insulation**						
8.8.4.1	Mechanical strength and resistance to heat	8.8.4.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.8.4.2	Resistance to environmental stress	8.8.4.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**						
8.9.1	Values	8.9.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.9.2	Applications	8.9.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.9.3	Spaces filled by insulating compound	8.9.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES	8.9.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1

8.10	**Components and wiring**						
8.10.1	Fixing of components	8.10.1	IS 13450 (Part 1)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.10.2	Fixing of wiring	8.10.2	IS 13450 (Part 1)	R			
8.10.3	Connections between different parts of ME EQUIPMENT	8.10.3	IS 13450 (Part 1)	R			
8.10.4	Cord-connected HAND-HELD parts and cord- connected foot-operated control devices	8.10.4	IS 13450 (Part 1)	R			
8.10.5	Mechanical protection of wiring	8.10.5	IS 13450 (Part 1)	R			
8.10.6	Guiding rollers for insulated conductors	8.10.6	IS 13450 (Part 1)	R			
8.10.7	Insulation of internal wiring	8.10.7	IS 13450 (Part 1)	R			
8.11	**MAINS PARTS, components and layout**						
8.11.1	Isolation from Supply mains	8.11.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer Note 1,3
8.11.2	Multiple Socket Outlets	8.11.2 8201.8.11.2	IS 13450 (Part 1) IS 13450 (Part 2/Sec 12)	S	One	Once in 03 years	Refer note 1
8.11.3	**Power Supply Cords**						

8.11.3.1	Application	8.11.3.1	IS 13450 (Part 1)	R	One		Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.11.3.2	Types	8.11.3.2	IS 13450 (Part 1)	R				
8.11.3.3	Cross-sectional area of POWER SUPPLY CORD conductors	8.11.3.3	IS 13450 (Part 1)	R				
8.11.3.4	Appliance Couplers Cord anchorage Cord guards	8.11.3.4 8.11.3.5 8.11.3.6	IS 13450 (Part 1) or IS/IEC 60320-1	R				
8.11.4	Mains terminal devices	8.11.4	IS 13450 (Part 1)	R				
8.11.5	Mains fuses and over current releases	8.11.5	IS 13450 (Part 1)	R				
8.11.6	Internal wiring of the Mains Part	8.11.6	IS 13450 (Part 1)	R				
201.9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**							
9.1	MECHANICAL HAZARDS of ME EQUIPMENT	9.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1	
9.2	MECHANICAL HAZARDS associated with moving parts	9.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1	
9.3	MECHANICAL HAZARD associated with surfaces, corners and edges	9.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1	
9.4	Instability HAZARDS	9.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1	

9.5	Expelled parts HAZARD	9.5	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
9.6	Audible acoustic energy	9.6 201.9.6.2.1.101	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 12)	S	One	Once in 03 years	Refer note 1
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure	9.7	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
9.8	MECHANICAL HAZARDS associated with support systems	9.8	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
201.9.101	Additional requirements for suction procedures	201.9.101	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.10	**Protection against unwanted and excessive radiation HAZARDS**						
10.1	X-Radiation	10.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
10.2	Alpha, beta, gamma, neutron and other particle radiation	10.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
10.3	Microwave radiation	10.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
10.4	Lasers	10.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
10.5	Other visible electromagnetic radiation	10.5	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
10.6	Infrared radiation	10.6, 201.10.6	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 21)	S	One	Once in 03 years	Refer note 1
10.7	Ultraviolet radiation	10.7	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1

201.11	**Protection against excessive temperatures and other HAZARDS**						
11.1	Excessive temperatures in ME EQUIPMENT	11.1 201.11.1.2.2	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 12)	S	One	Once in 03 years	Refer note 1
11.2	Fire Prevention	11.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	11.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	11.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	11.5	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	11.6, 201.11.6.5.101 201.11.6.6 201.11.6.7	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 12) IS 13450 (Part 2/ Sec 12) IS 13450 (Part 2/ Sec 12)	R	One	Every Medical Equipment	
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	11.7 201.11.7	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 12)	S	One	Once in 03 years	Refer note 1
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	11.8 201.11.8.101	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 12)	S	One	Once in 03 years	Refer note 1

201.12	**Accuracy of controls and instruments and protection against hazardous outputs**						
201.12.1	Accuracy of controls and instruments	201.12.1	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.12.1.101	Volume-control inflation-type	201.12.1.101	IS 13450 (Part 2/ Sec 12)	R			
201.12.1.102	Pressure-control inflation-type	201.12.1.102	IS 13450 (Part 2/ Sec 12)	R			
201.12.1.102	3Other inflation-types	201.12.1.103	IS 13450 (Part 2/ Sec 12)	R			
201.12.1.104	Inspiratory volume monitoring	201.12.1.104	IS 13450 (Part 2/ Sec 12)	R			
201.12.1.105	Response of the ventilator to an increase in set O2 concentration	201.12.1.105	IS 13450 (Part 2/ Sec 12)	R			
12.2	USABILITY of ME EQUIPMENT	12.2 201.12.2	IS 13450 (Part 1)	R	One	Each Medical Equipment	
12.3	ALARM SYSTEMS	12.3	IS 13450 (Part 1)	R	One	Each Medical Equipment	
12.4	Protection against hazardous output	12.4.1 12.4.2 12.4.3 12.4.4	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
201.12.4.101	Oxygen monitor	201.12.4.101	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.12.4.102	Measurement of airway pressure	201.12.4.102	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.12.4.103	Measurement of expired volume and low volume alarm	201.12.4.103.1 201.12.4.103.2	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	

	conditions						
201.12.4.104	Expiratory end-tidal CO2 monitoring equipment	201.12.4.104	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.12.4.105	Maximum limited pressure protection device	201.12.4.105	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.12.4.106	High airway pressure alarm condition and protection device	201.12.4.106	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.12.4.107	PEEP alarm conditions	201.12.4.107	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.12.4.108	Obstruction alarm condition	201.12.4.108	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.12.4.109	Disconnection alarm condition	201.12.4.109	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.12.4.110	Protection against inadvertent setting of high airway pressure	201.12.4.110	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.12.101	Protection against accidental or unintentional adjustments	201.12.101	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.13	**HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT**						
13	HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	13	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1

201.13.2.101	Additional specific single fault conditions	201.13.2.101	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.13.2.102	Failure of one gas supply to a ventilator	201.13.2.102	IS 13450 (Part 2/ Sec 12)	R			
201.13.2.103	Independence of ventilation control function and related risk control measures	201.13.2.103	IS 13450 (Part 2/ Sec 12)	R			
201.13.2.104	Failure of functional connection to a ventilator control or monitoring means	201.13.2.104	IS 13450 (Part 2/ Sec 12)	R			
201.14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**						
201.14.101	Software life cycle	14	IEC 62304:2006	S	One	Once in 03 years	Refer note 1
15	**Construction of ME EQUIPMENT**						
15.1	Arrangements of controls and indicators of ME EQUIPMENT	15.1	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
15.2	Serviceability	15.2	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
15.3	Mechanical strength	15.3	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
201.15.3.5.101	Additional requirements for rough handling	201.15.3.5.101 201.15.3.5.102	IS 13450 (Part 2/ Sec 12)	S	One	Once in 03 years	Refer note 1
201.15.4.1	Construction of connectors	201.15.4.1	IS 13450 (Part 2/ Sec 12)	S	One	Once in 03 years	Refer note 1
201.15.101	Mode of operation	201.15.101	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	

201.15.102	Delivered oxygen concentration	201.15.102	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.15.103	Accessory self-check	201.15.103	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.16	**ME SYSTEMS**						
201.16.1.101	Additional general requirements for ME systems	201.16.1.101	IS 13450 (Part 2/ Sec 12)	S	One	Once in 03 years	Refer note 1
201.16.2.101	General requirements for the ME SYSTEMS	201.16.2.101	IS 13450 (Part 2/ Sec 12)	S	One	Once in 03 years	Refer note 1
201.17	**Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS**						
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	17	IS 13450 (Part 1)	S	One	Once in 03 years	Refer note 1
201.101	Gas connections	201.101	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.102	Requirements for the VBS and accessories	201.102	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.103	Spontaneous breathing during loss of power supply	201.103	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.104	Indication of duration of operation	201.104	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.105	Functional connection	201.105	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	

201.106	Display loops	201.106	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
201.107	Timed ventilatory pause	201.107	IS 13450 (Part 2/ Sec 12)	R	One	Each Medical Equipment	
202	**Electromagnetic disturbances – Requirements and tests**						
202	Electromagnetic disturbances – Requirements and tests	202	IS 13450 (Part 1/ Sec 2) IS 13450 (Part 2/Sec 12)	S	One	Once in 03 years	Refer note 1
206	Usability	206	IS 13450 (Part 2/ Sec 12)	S	One	Once in 03 years	Refer note 1
208	General requirements, tests and guidance for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS	208	IS 13450 (Part 2/ Sec 12)	S	One	Once in 03 years	Refer note 1

Note-1: In addition, the test(s) shall be done whenever there is a change in design of the product, components or parts.

Note-2: Report of the Factory Sample drawn for complete testing by BIS will be shared with the manufacturer. During the operation of licence, licensee has to ensure that all the model(s) covered in the scope of the licence are tested in rotation.